

**NATIONAL  
MARROW  
DONOR  
PROGRAM®**

Entrusted to operate the C.W. Bill Young Cell Transplantation Program,  
including Be The Match Registry®

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November 11, 2010

CDR Sheri Parker  
Office of Naval Research (ONR 342)  
875 N. Randolph St.  
Arlington, VA 22203-1995

**Subject: Quarterly Performance/Technical Report of the National Marrow Donor Program®**

**Reference:** Grant Award #N00014-10-1-0204 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Parker:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of July 1, 2010 to September 30, 2010.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at [cabler@nmdp.org](mailto:cabler@nmdp.org)).

Sincerely,



Carla Abler-Erickson, MA  
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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# REPORT DOCUMENTATION PAGE

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14. ABSTRACT <p><u>1. Contingency Preparedness:</u> Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.</p> <p><u>2. Rapid Identification of Matched Donors :</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.</p> <p><u>3. Immunogenetic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation.</p> <p><u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.</p>					
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NATIONAL MARROW DONOR PROGRAM®

*Creating Connections. Saving Lives.™*

Grant Award N00014-10-1-0204

QUARTERLY  
PERFORMANCE / TECHNICAL REPORT  
FOR  
JULY 01, 2010 to SEPTEMBER 30, 2010  
PERIOD 2

Office of Naval Research

And

The National Marrow Donor Program  
3001 Broadway Street N.E.  
Minneapolis, MN 55413  
1-800-526-7809

**QUARTER PROGRESS REPORT****Development of Medical Technology for Contingency Response to Marrow Toxic Agents****July 01, 2010 through September 30, 2010**

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**IIA. Contingency Preparedness – Objective 1:** Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians

<b>IIA.1. Task 1:</b> Secure Interest of Transplant Physicians	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• 23 staff from Radiation Injury Treatment Network (RITN) centers completed advanced radiation emergency medicine training at the Radiation Emergency Assistance Center/Training Site (REAC/TS).</li> <li>• 244 new RITN staff members successfully completed the Basic Radiation Training Course (2240 total have been trained since 2006).</li> </ul>
<b>IIA.1. Task 2:</b> GCSF in Radiation Exposure	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• No activity this period.</li> </ul>
<b>IIA.1. Task 3:</b> Patient Assessment Guidelines and System Enhancements	<b>Period 2 Activity:</b> <p>Donor Management tool application efforts were focused on prioritized enhancements for the Navy Contingency project.</p> <p>This project promotes electronic contact with donors via email and allows them to update their contact information and complete an online Health History Questionnaire (HHQ) from the Do It Yourself Donor online platform. Information provided by the donor is securely transferred to the donor's record in the tool used to manage Donor Activity; facilitating reporting, storage and review of this information in established donor management systems.</p> <p>Project Outcomes, related to the new versions of the tools used to manage Donor Activity, continue to show favorable results and strong user feedback:</p> <ul style="list-style-type: none"> <li>• Donors continue to be responsive to online tools. New Online Health History Questionnaire functionality resulted in: <ul style="list-style-type: none"> <li>○ 8,471 "Completed" HHQs</li> <li>○ 470 "in process" HHQs</li> </ul> </li> </ul>

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	<p>between 10/1/09 – 09/30/10</p> <ul style="list-style-type: none"> <li>An overall time savings of 1,624 hours for completed HHQs due to the 50% reduction in processing time per Online HHQ.</li> </ul> <p>Navy Contingency Project Pilot Release 2</p> <p>The Event Portal Workflow Management Application to manage contingency events (<i>initially for preliminary search event,</i>) is in production for all Domestic NMDP Network Donor Centers, excluding the DoD, DKMS Americas, Gift of Life Registry and Caitlyn Raymond Registry.</p> <p>Key features included in this Release are the ability to:</p> <ul style="list-style-type: none"> <li>Ability to track preliminary event donors in a central screen, for purposes of donor management.</li> <li>Ability to import the preliminary event donors, as identified through the preliminary event daily report</li> <li>Ability to export the preliminary event donors for purpose of supporting address validations, manual mail merges or automated letter merges</li> </ul> <p>Key statistics gathered to date for the Event Portal:</p> <ul style="list-style-type: none"> <li>5,197 Preliminary Search HHQs were completed</li> <li>2,141 Preliminary Search donors were activated</li> <li>7 days is the average close date on an Preliminary Search HHQ</li> </ul> <p>The Event Portal Workflow Management functionality has added to the productivity gains of donors screened using this method, it is expected that NMDP will gain:</p> <ul style="list-style-type: none"> <li>The capability to double the capacity to process an HHQ using the same number of staff resources.</li> <li>The ability to scale for a contingency event requiring confirmation of the availability and suitability of a large number of donors.</li> </ul>
IIA 1. Task 4: National Data Collection Model	<p><b>Period 2 Activity:</b></p> <ul style="list-style-type: none"> <li>No activity this period.</li> </ul>

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**IIA. Contingency Preparedness – Objective 2:** Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

**IIA.2. Task 1:**  
Contingency  
Response Network

**Period 2 Activity:**

- Nineteen of 54 active RITN centers completed their required participation tasks as of September 30, 2010.
  - Each RITN center must accomplish assigned tasks to receive payment for their activities related to improving the national preparedness efforts for responding to a mass casualty incident resulting in marrow toxic injuries.
  - These tasks include; maintaining or creating an SOP, conducting an NMDP directed tabletop exercise and conducting training.
- NMDP staff member attended the University of Alabama, Birmingham (September 17, 2010) tabletop exercise to observe, collect feedback to improve the FY11 tabletop exercise and provide support as requested to RITN center staff.
- NMDP coordinated a web based best practices presentation by Memorial Sloan Kettering Cancer Center for RITN center staff, which was attended by over 50 RITN center members.
- Continued to consult with the National Security Council on options to significantly increase the networks capabilities, seeking opportunities to increase the awareness of RITN and identify possible additional funding sources.
- Training materials for the evaluator exchange program were improved upon; already developed materials include evaluation checklists to assess of preparedness of RITN transplant centers.
- Coordinated with Dartmouth Medical School's - New England Center for Emergency Preparedness to allow access to Health Care Standard (NCS) software at no charge to the NMDP and RITN; this software will eventually replace WebEOC for emergency communications and coordination.
- Initiated resigning of MOA for satellite telephones issued to RITN centers.



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<b>IIA.2. Task 2:</b> Sibling Typing Standard Operating Procedures	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• Finalized the design of a manual process to test the HLA typing of related donors for victims of a mass casualty incident resulting in marrow toxic injuries. This process is necessary incase such a disaster were to occur before the full implementation of an integrated process.</li> <li>• We are conducting a business case assessment to fully define the Business and System Requirements to incorporate a related typing process into the existing NMDP systems for use during a mass casualty incident resulting in marrow toxic injuries.</li> </ul>
<b>IIA. Contingency Preparedness – Objective 3:</b> NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
<b>IIA.3. Task 1:</b> I.S. Disaster Recovery	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• No activity this period.</li> </ul>
<b>IIA.3. Task 2:</b> Critical Facility and Staff Related Functions	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• Conducted the second annual organizational level functional exercise for business continuity (BCPex2010) at the Roseville Radisson Hotel August 31- September 2, 2010.             <ul style="list-style-type: none"> <li>○ 47 NMDP staff participated from seven departments.</li> <li>○ Participating departments validated their ability to execute identified critical tasks from a remote location following a disaster making their primary workplace unavailable.</li> <li>○ Exercise objectives included:                 <ul style="list-style-type: none"> <li>▪ Establish data center connectivity from an ad hoc Critical Staff Recovery Site.</li> <li>▪ Establish Unified Communications at ad hoc Critical Staff Recovery Site.</li> <li>▪ Assess ability of participating department staff to complete critical tasks.</li> <li>▪ Capture shortcomings and develop corrective action plan.</li> </ul> </li> <li>○ Critical Tasks Successfully Accomplished by department:                 <ul style="list-style-type: none"> <li>▪ Be the Match Foundation (100%)</li> <li>▪ Donor Resources (100%)</li> </ul> </li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>▪ LRNA (66% - Staff not available from Purchasing and Contracts due to Oracle implementation meetings)</li> <li>▪ Patient Services (75% - one application was not available remotely)</li> <li>▪ Quality Systems (100%)</li> <li>▪ Scientific Services (90% - one application was not available remotely)</li> <li>▪ Search &amp; Transplant (100%)</li> </ul> <ul style="list-style-type: none"> <li>• Site visit was conducted at the NMDP operated donor center in Saginaw, MI (September 24, 2010) <ul style="list-style-type: none"> <li>○ At these site visits the Business Continuity Planner reviews the Business Continuity Action Guide with staff to better prepare each location for responding to incidents that interrupt operations ranging from power or Internet outages to severe weather.</li> </ul> </li> <li>• Received 50 mobile broadband air cards at minimal cost to the organization and ONR to allow for immediate access to the NMDP Data Center in the event that the Coordinating Center is not accessible. This will ensure that staff with the highest priority to continue work will be able to work from any location following initiation of the Business Continuity Plan.</li> </ul>
<b>IIB. Rapid Identification of Matched Donors – Objective 1:</b> Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
<b>IIB.1. Task 1:</b> Increase Registry Diversity	<b>Period 2 Activity:</b> <p>Five contracted HLA testing laboratories performed HLA-A, B, DRB1 typing, two laboratories performed HLA-A, B, C, DRB1 typing, on a total of 25,856 newly recruited donors.</p> <ul style="list-style-type: none"> <li>• Blind quality control testing error rate was 0.10%, meeting the project requirement of <math>\leq 2.0\%</math>.</li> <li>• On-time testing completion rate was 98.0%, meeting the project requirement of a minimum of 90% of typing results reported within 14 days of shipment of samples.</li> </ul> <p>Request for Proposal (RFP)</p> <p>As a result of RFP C10-0001, seven laboratories were awarded agreements for the HLA Typing of Registry Donors. This agreement period is from June 28, 2010 to June 26, 2011. The selection of these laboratories has allowed the NMDP to make significant changes to this program:</p> <ul style="list-style-type: none"> <li>• Percent of donors typed at HLA-C increased from 34% to 45%</li> </ul>

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	<ul style="list-style-type: none"> <li>• Percent of donors typed by Sequence Based Typing (SBT) methodology increased from 11% to 41%. SBT provides a higher level of typing resolution.</li> <li>• Diversity of typing reagents utilized by the laboratories increased. The percent of samples typed by one reagent vendor decreased from 73% to 59%.</li> <li>• Sample capacity increased from 15,000 samples per week to 18,000 samples per week.</li> <li>• Geographic diversity of laboratory location improved by adding a laboratory on the west coast.</li> <li>• The average cost per sample decreased by 6.9%.</li> </ul> <p>During this past quarter, as an ongoing project of reviewing rare alleles reported on donors in the Be The Match Registry, 270 additional donors with one or more rare alleles were identified and retyped. To date, 532 samples have been sent to a contract laboratory for high resolution typing at A, B, or DRB1. In total, 582 (71%) donor typings have changed from the previously reported rare allele and 235 donor typings have been confirmed to carry a rare allele. An abstract summarizing these data was presented as a poster at the ASHI annual meeting in Sept. 2010.</p>
<b>IIB.1. Task 2:</b> Evaluate HLA- DRB1 High Res typing	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• This task is closed.</li> </ul>
<b>IIB.1. Task 3:</b> Evaluate HLA-C Typing of Donors	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• This task is closed.</li> </ul>
<b>IIB.1. Task 4:</b> Evaluate Buccal Swabs	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• No activity this period.</li> </ul>
<b>IIB 1. Task 5:</b> Enhancing HLA Data for Selected Donors	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• No activity this period.</li> </ul>
<b>IIB 1. Task 6:</b> Maintain a Quality Control Program	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>• No activity this period.</li> </ul>

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**IIB. Rapid Identification of Matched Donors – Objective 2:** Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.

<b>IIB 2. Task 1:</b> Collection of Primary Data	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>No activity this period.</li> </ul>
<b>IIB 2. Task 2:</b> Validation of Logic of Primary Data	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB 2. Task 3:</b> Reinterpretation of Primary Data	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB 2. Task 4:</b> Genotype Lists & Matching Algorithm	<b>Period 8 Activity:</b> <ul style="list-style-type: none"> <li>Continued working on operationalizing the code in order to interpret all incoming SBT typings in real-time. <ul style="list-style-type: none"> <li>Composed an HML Data Dictionary document which offers an overview and comparison of several versions of HML,</li> <li>Began adding SBT interpretation to the Star2 probe interpretation, and adding support for HML version 0.3.3 to Star2.</li> <li>An abstract summarizing the progress of accepting and interpreting primary SBT data was presented at the ASHI annual meeting in September 2010.</li> </ul> </li> </ul>

**IIB. Rapid Identification of Matched Donors – Objective 3:** Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.

<b>IIB.3. Task 1:</b> Phase I of EM Haplotype Logic	<b>Period 8 Activity:</b> <ul style="list-style-type: none"> <li>Worked on a technology port of the Search Server matching algorithm in order to increase stability and performance of the algorithm.</li> <li>Hired replacement business analyst to continue working on business and system requirements for HapLogic Phase III</li> </ul>
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<b>IIB 3. Task 2:</b> Enhancement of EM Algorithm	<b>Period 8 Activity:</b> <ul style="list-style-type: none"> <li>Created first draft of manuscript for full-registry high-resolution haplotype frequencies.</li> <li>Conducted analysis of effect on haplotype frequencies of sets of alleles that are rarely distinguished by current typing methods.</li> </ul>
<b>IIB 3. Task 3:</b> Optimal Registry Size Analysis	<b>Period 8 Activity:</b> <ul style="list-style-type: none"> <li>Created first drafts of results sections for 2 manuscripts on registry size analysis, one physician-oriented, one methods and registry-oriented.</li> <li>Performed cost-benefit analysis comparing the value of adult donor recruitment versus CBU recruitment. Results indicate that NMDP should have a larger CBU inventory given the current size of the adult donor registry.</li> <li>Calculated optimal minimum TNC for CBU recruitment for adult patients to be <math>155 \times 10^7</math> TNC rather than the current HRSA guideline of <math>90 \times 10^7</math> TNC.</li> </ul>
<b>IIB 3. Task 4:</b> Target Under- Represented Phenotypes	<b>Period 8 Activity:</b> <ul style="list-style-type: none"> <li>Engaged a consultant with the help of Environmental Systems Research Institute (ESRI) to automate map production for large numbers of HLA files. Automation was completed during this period.</li> <li>Continued building a comprehensive database to hold all research data. Modeled database to align with caBIG/BRIDG 3.0 model</li> </ul>
<b>IIB 3. Task 5:</b> Bioinformatics Web Site	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB 3. Task 6:</b> Consultants to Improve Algorithm	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB 3. Task 7:</b> Population Genetics	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>

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<b>IIB 3. Task 8:</b> Haplotype Matching	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB 3. Task 9:</b> Global Haplotype/Benchmark	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB. Rapid Identification of Matched Donors – Objective 4:</b> Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
<b>IIB.4. Task 1:</b> Expand Network Communications	<b>Period 2 Activity:</b> <p>Extended the Business to Business (B2B) Services to support the new alleles and allele combinations expressed as allele codes. Also provided:</p> <ul style="list-style-type: none"> <li>Limited Support for WHO approved P groups</li> <li>Full support of WMDA approved codes – XXXX, NNNN, UUUU, NEW.</li> <li>Support in external tools for user queries of allele code information</li> <li>Preparation for expansion of allele code information</li> <li>Support for new nomenclature vendor DNA typing kits</li> </ul> <p>NMDP has initiated development on a B2B implementation of a Cord Blood Unit inventory exchange model. The following have been completed:</p> <ul style="list-style-type: none"> <li>Development of modifications to B2B database schema to support inventory sharing</li> <li>Development of new B2B Gateway database schema to support transaction sharing</li> <li>Began development of the components required to share NMDP cord blood unit inventory with strategic partners, and to keep it updated.</li> <li>Exchanged test cord blood inventory messages with several partners.</li> <li>Documented semantics describing the messages and process flow to exchange inventory.</li> <li>Documented fields that each will be sending in the inventory exchange.</li> <li>Shared house rules for searching based on CBU status, no differences or concerns.</li> </ul>

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	<ul style="list-style-type: none"> <li>Agreed that since ownership of data resides with the source registry, the mirroring registry will only update a CBU's search antigens when a CBU change is received from the source registry; the search antigens will not be updated by the non-owner when lab results are received.</li> </ul>
<b>IIB.4. Task 2:</b> Central Contingency Management	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>No activity this period.</li> </ul>
<b>IIB.4. Task 3:</b> Benchmarking Analysis	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIB.4. Task 4:</b> Expand Capabilities of Collection and Apheresis Centers	<b>Period 2 Activity:</b> <ul style="list-style-type: none"> <li>This task is closed.</li> </ul>
<b>IIC. Immunogenetic Studies – Objective 1:</b> HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
<b>IIC.1. Task 1:</b> Donor Recipient Pair Project	<b>Period 2 Activity:</b> <p>In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies. Presence/absence typing of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) has been included.</p> <ul style="list-style-type: none"> <li>Typing of SG 26 came to a close on August 31, 2010.</li> <li>175 cord/recipient pairs were selected for SG 27. The period of performance began August 31, 2010 and will close on December 31, 2010. All 175 pairs will be typed for HLA and KIR. Whole Genome Amplified (WGA) DNA from 98 samples will be used in the SG.</li> </ul>

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	<ul style="list-style-type: none"> <li>To date over 2000 pairs from the Donor/Recipient pair project have been typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) and another 1180 donors have been typed.</li> </ul> <p>Current HLA matching guidelines for unrelated HCT recommend avoidance of mismatches only within the Antigen Binding Domain (ABD). This recommendation is based on the hypothesis that amino acid differences outside the ABD are not immunogenic. The ABD allo-reactivity assessment project will give insight into the allowable percent tolerance of matching needed outside of the ABD.</p> <ul style="list-style-type: none"> <li>Initiated investigation of the first class II non-ABD mismatch (DRB1*140101/1454) where both alleles have been seen in the same genotype. Specific queries of the Be The Match Registry allowed for selection of ninety-nine potential donors to be typed at high resolution.</li> <li>72 donors were invited to participate in the study. 21 study participants consented and submitted blood samples. Samples were cryopreserved at a centralized laboratory and will be distributed for testing in the next quarter.</li> </ul>
<b>II.C. Immunogenetic Studies – Objective 2:</b> Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
<b>II.C.2. Task 1:</b> Analysis of non-HLA loci	<b>Period 2 Activity:</b> <b>KIR</b> <p>In 2005 a pilot study to perform high resolution KIR gene typing was launched. The primary objectives of the study were to move technology forward from the current practice of locus level typing to high resolution typing, disseminate information and protocols in an open source mechanism and develop reference lines for use in individual laboratories.</p> <ul style="list-style-type: none"> <li>All 46 novel alleles have been submitted and names received. Publication of the new IPD database containing these alleles is expected within the next year. A publication is in development to describe the typing of the new alleles.</li> <li>Preparation continued on the KIR Typing Project manuscript.</li> </ul>



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	<p><b>Bioinformatics</b></p> <p>The Immunobiology Project Results (IPR) database and its applications will allow for storage and analysis of all immunogenetic data collected on NMDP research samples. This database will replace the existing HLA donor/recipient pair's database and facilitate storage and analysis of data from other immunogenetic loci (KIR, microsatellites, single nucleotide polymorphisms, etc).</p> <p>During Period 8:</p> <ul style="list-style-type: none"> <li>• Software tools that monitor and resolve typing discrepancies were released to production.</li> <li>• Development and quality assurance was completed on the Audit Report and Audit Tool.</li> <li>• Development was initiated to support version three nomenclature.</li> <li>• Development was renewed which will migrate data from the 'High Resolution' database into IPR.</li> </ul>
<b>IIC 2. Task 2:</b> Related Pairs Research Repository	<p><b>Period 2 Activity:</b></p> <p>Related transplant research sample collection continued as a pilot project with 5 TCs submitting 178 samples (80 donor/recipient pairs) to the repository. Since inception of the project in December 2007, the repository has received 1,371 samples (610 pairs). An invitation to enroll in the project was extended to 64 centers from the Bone and Marrow Transplant Clinical Trials Network, and 30 BMTCTN centers have agreed to participate. Following local IRB approval, sample collection should begin next quarter. Development and enhancements continue on the Research Sample Repository Tools suite to facilitate management and reporting of sample inventory.</p>
<b>IIC 2. Task 3:</b> CIBMTR Integration	<p><b>Period 2 Activity:</b></p> <ul style="list-style-type: none"> <li>• This task is closed.</li> </ul>
<b>IID. Clinical Research in Transplantation – Objective 1:</b> Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
<b>IID.1. Task 1:</b> Observational Research, Clinical Trials and NIH Transplant Center	<p><b>Period 2 Activity:</b></p> <p><b>Cord Blood Research</b></p> <ul style="list-style-type: none"> <li>• The Duke and MD Anderson laboratory staff continued work on validating the assay methodologies to ensure consistent results were generated at both testing sites for the study</li> </ul>

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investigating biomarkers associated with cord blood engraftment.

- The study team has held multiple conference calls to discuss the possible areas in which variation could have been introduced into the assays protocols.
  - The laboratory staff is conducting additional validation studies to determine study progression feasibility.
- Work continued on the observational study of single versus double cord blood transplants in adults. The study cohort is being expanded to include participants from 2007 and 2008. The principal investigator, EJ Shpall, MD, will present an update on the progress of the study at the NMDP Cord Blood Advisory Group meeting in October. A draft manuscript is in process.
- Adult Double Cord trial activity included two patients enrolling, bringing total enrollment to 38 patients, for a 69 % completion rate. Staff continues to coordinate and complete monthly PI and coordinator calls, manage data collection and monitor sites.
- Maternal samples and HLA typing data were collected from participating CBBs to gather the necessary maternal HLA typing information for the NIMA study. Samples were tested and all of the typing data were collated. NIMA match coding was performed and data was sent to the CIBMTR for analysis.
- Work continued on the development of a white paper detailing recommendations/guidelines for the assessment of new assays (potency or other assays) relevant to cord blood banking and/or transplantation. The final version of the paper was completed in September and prepared for submission to Cytotherapy.
- Duke, MD Anderson, Puget Sound, and St. Louis laboratory staff began working with Stem Cell Technologies to assess the efficacy of STEMvision, an automated CFU enumeration instrument.

**Observational Research**

- Staff continued work on various observational studies within the area of Immunobiology, GVHD and Graft Sources Working Committees. Five abstracts were submitted and accepted to the American Society of Hematology annual meetings during this reporting period.

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	<p><b>Prospective Studies; RCI BMT</b></p> <ul style="list-style-type: none"> <li>• During this report period, follow up activities continued for donors participating in the PBSC vs. Marrow clinical trail. Staff continue to support this activity including monitoring.</li> <li>• Adult Double Cord trial activity during this period included two patients being enrolled for a total of thirty eight patients accrued to this study, giving us a 69% completion rate. Staff continues to coordinate and complete monthly PI and coordinator calls, manage data collection and monitor sites.</li> <li>• The survey research team continues to develop processes and add staff to support studies requiring their expertise.</li> <li>• Staff continued to work on identifying and streamlining the operational processes needed to implement the protocol for long-term donor follow-up.</li> </ul> <p><b>NIH Transplant Center</b></p> <ul style="list-style-type: none"> <li>• NMDP provided support for donor identification, selection and collection for the NIH intramural unrelated donor transplant program. Activity in the last quarter was as follows: <ul style="list-style-type: none"> <li>○ 14 formal searches</li> <li>○ 46 donor confirmatory typing blood sample and IDM testing requests</li> <li>○ 40 cord blood unit confirmatory typing requests</li> <li>○ 11 PBSC collections</li> <li>○ 4 cord blood shipments</li> </ul> </li> </ul>
<b>IID.1. Task 2:</b> Research with NMDP Donors	<p><b>Period 2 Activity:</b></p> <ul style="list-style-type: none"> <li>• This task is closed.</li> </ul>

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biology Research**Period 2 Activity:**

The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies

- The co-scientific director attended the Center-specific Outcome Analysis forum in Milwaukee, WI
- Three manuscripts were accepted for publication:
  - Ann Woolfrey, et al., HLA-C antigen mismatches are associated with worse outcomes in unrelated donor peripheral blood stem cell transplantation. BBMT 2010 Sept 23 [Epub ahead of print]
  - Peter Shaw, et al., Outcomes of pediatric BMT for leukemia and myelodysplasia using matched sibling, mismatched related or matched unrelated donors. Blood 2010 July 29 [Epub ahead of print]
  - David Valcarcel, et al., One antigen mismatched related vs. HLA-matched unrelated donor HCT in adults with acute leukemia: CIBMTR results in the era of molecular typing. BBMT 2010 July 29 [Epub ahead of print].
- One manuscript was submitted for publication:
  - Lujia Dong, et al., The outcomes of family haploidentical hematopoietic stem cell transplantation in hematological malignancies are not associated with patient age. Rejected by Blood. Submitted to BBMT.
- One abstract was submitted to the 2010 ASH Annual Meeting
  - Bronwen Shaw, et al., Permissive HLA-DPB1 mismatching compared to a non-permissive mismatching significantly improves overall survival following allogeneic transplantation in patients with both 10/10 and 9/10 matched unrelated donors. ASH Annual Meeting 2010.

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## ACRONYM LIST

AABB	American Association of Blood Banks	IBWC	Immunobiology Working Committee
AFA	African American	IDM	Infectious Disease Markers
AGNIS	A Growable Network Information System	IHWG	International Histocompatibility Working Group
AML	Acute Myelogenous Leukemia	IPR	Immunobiology Project Results
ABD	Antigen Binding Domain	ICRHER	International Consortium for Research on Health Effects of Radiation
API	Asian Pacific Islander	IND	Investigational New Drug
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IS	Information Services
ASBMT	American Society for Blood and Marrow Transplantation	IT	Information Technology
ASHI	American Society for Histocompatibility and Immunogenetics	IRB	Institutional Review Board
B-LCLs	B-Lymphoblastoid Cell Lines	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BARDA	Biomedical Advanced Research and Development Authority	KIR	Killer Immunoglobulin-like Receptor
BCPeX	Business Continuity Exercise	MDACC	MD Anderson Cancer Center
BBMT	Biology of Blood and Marrow Transplant	MDS	Myelodysplastic Syndrome
BMT	Bone Marrow Transplantation	MHC	Major Histocompatibility Complex
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICA	MHC Class I-Like Molecule, Chain A
BRT	Basic Radiation Training	MICB	MHC Class I-Like Molecule, Chain B
C&A	Certification and Accreditation	MKE	Milwaukee
CAU	Caucasian	MSKCC	Memorial Sloan-Kettering Cancer Center
CBMTG	Canadian Blood and Marrow Transplant Group	MSP	Minneapolis
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NCBM	National Conference of Black Mayors
CBS	Canadian Blood Service	NCI	National Cancer Institute
CBU	Cord Blood Unit	NEMO	N-locus Expectation-Maximization using

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			Oligonucleotide typing data
CHTC	Certified Hematopoietic Transplant Coordinator	NHLBI	National Heart Lung and Blood Institute
CIBMTR	Center for International Blood & Marrow Transplant Research	NIH	National Institutes of Health
CIT	CIBMTR Information Technology	NIMS	National Incident Management System
CLIA	Clinical Laboratory Improvement Amendment	NK	Natural Killer
CME	Continuing Medical Education	NLE	National Level Exercise
CMF	Community Matching Funds	NMDP	National Marrow Donor Program
COG	Children's Oncology Group	NRP	National Response Plan
CREG	Cross Reactive Groups	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CSS	Center Support Services	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CT	Confirmatory Testing	OIT	Office of Information Technology
CTA	Clinical Trial Application	OMB	Office of Management and Budget
DC	Donor Center	ONR	Office of Naval Research
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	P2P	Peer-to-Peer
DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DoD	Department of Defense	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
D/R	Donor/Recipient	RCC	Renal Cell Carcinoma
EBMT	European Group for Blood and Marrow Transplantation	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EM	Expectation Maximization	REAC/TS	Radiation Emergency Assistance Center/Training Site
EMDIS	European Marrow Donor Information System	RFP	Request for Proposal
ENS	Emergency Notification System	RFQ	Request for Quotation
ERSI	Environment Remote Sensing Institute	RG	Recruitment Group
FBI	Federal Bureau of Investigation	RITN	Radiation Injury Treatment Network

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FDA	Food and Drug Administration	SBT	Sequence Based Typing
FDR	Fund Drive Request	SCTOD	Stem Cell Therapeutics Outcome Database
Fst	Fixation Index	SG	Sample Group
GETS	Government Emergency Telecommunications Service	SLW	STAR Link® Web
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SSA	Search Strategy Advice
GIS	Geographic Information System	SSO	Sequence Specific Oligonucleotides
GvHD	Graft vs Host Disease	SSP	Sequence Specific Primers
HCT	Hematopoietic Cell Transplantation	SSOP	Sequence Specific Oligonucleotide Probes
HEPP	Hospital Emergency Preparedness Program	STAR®	Search, Tracking and Registry
HHQ	Health History Questionnaire	TC	Transplant Center
HHS	Health and Human Services	TED	Transplant Essential Data
HIPAA	Health Insurance Portability and Accountability Act	TNC	Total Nucleated Cell
HIS	Hispanic	TSA	Transportation Security Agency
HLA	Human Leukocyte Antigen	UI	User Interface
HML	Histoimmunogenetics Mark-up Language	URD	Unrelated Donor
HR	High Resolution	WGA	Whole Genome Amplification
HRSA	Health Resources and Services Administration	WMDA	World Marrow Donor Association
HSC	Hematopoietic Stem Cell	WU	Work-up